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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,093	02/02/2004	Marcia K. Wolf	034047.033.4	6121

7590 04/24/2006

Office of the Staff Judge Advocate
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-JA (Ms. Elizabeth Arwine)
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER

GRASER, JENNIFER E

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/768,093	Applicant(s) WOLF ET AL	
	Examiner Jennifer E. Graser	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11,16-22,25,26 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,11,16-19 and 31 is/are rejected.
- 7) ☒ Claim(s) 20-22 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/2/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Examiner of Record has changed from Virginia Portner to Jennifer Graser.

Election/Restrictions

Applicant's election with traverse of Group I, claims 10, 11, 25, 26 and 31 in the reply filed on 1/26/06 is acknowledged. The traversal is on the ground(s) that the methods use the protein of Group I and it would not place an undue burden on the Examiner to search the methods with the claim. Applicants' arguments are persuasive and the method claims (claims 16-22) have been rejoined.

Claims 10, 11, 16-22, 25, 26 and 31 are currently under examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites that the polypeptide is administered in the form of a 'host that expresses the polypeptide'. This term is vague and confusing because it is unclear what else besides a cell would have the ability to express the polypeptide.. It appears that Applicants intend to recite 'host cell'. Correction is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1645

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10, 11, 25 and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Wolf et al (different inventive entity) (Submitted. Jan. 1994. UniProt Accession # P53509).

Wolf et al disclose a protein which is 100% identical to Applicants' SEQ ID NO: 9. The compositions of claims 11 and 25 only require the protein and therefore are anticipated by Wolf et al.

5. Claims 10, 11, 16, 17, 18, 19, 25 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al (1989, Infect.Immun. 57(1): 164-173).

Wolf et al. disclose compositions that comprise CS6 protein from *E.coli* E8775, the same strain from which the protein of SEQ ID NO: 9 was isolated. One of the disclosed compositions that comprised CS6 proteins was an agarose gel containing the CS6 16 kDa band (Figure 3, a type of acceptable carrier). An additional composition that comprised the W8775 CS6 protein was a saline extract of E8775 (see page 167, col. 1, paragraph 1). The protein was used to generate antisera. Additionally, it was shown that the whole cell bacterium raised antibodies against the CS6 protein. Wolf et al do not disclose the amino acid sequence of E8775 16kDa protein CS6, but the amino acid sequence of a protein is an inherent structural characteristic. Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. v IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the

Art Unit: 1645

inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient that is inherently contained in the prior art.

The disclosed protein of the prior art reference appears to be identical to Applicants' protein given the identity of the source. Since the Patent Office does not have the facilities for examining and comparing Applicant's BPIP with the BPIP of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed protein and the protein of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&).


6. Claims 20-22 and 26 are objected to as being dependent upon a rejected base claim.

7. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.


JENNIFER E. GRASER
PRIMARY EXAMINER
4/17/08